Date: September 14, 2005

CRITERIA FOR PRIOR AUTHORIZATION For Growth Hormone Therapy

<u>Appropriate NDC Code</u> (Item or Procedure Here)

<u>Human Growth Hormone</u> (Item or Procedure Here)

Provider Group: Pharmacy

Kansas Medicaid Prior Authorization for Growth Hormone for Children-Initial Request

Required for all:

- 1. Evaluation by Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
- 2. Height velocity, target height, and percentiles (SD) recommend calculations be made using software designed for that purpose. (Attach copy of printout to SMN).
- 3. Copy of growth curve.
- 4. Radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls)

Requests for prior authorization for GH therapy for children may be considered medically necessary for the following conditions: Panhypopituitarism, Documented endogenous GH deficiency, Chronic renal insufficiency, Turner's syndrome, and Prader-Willi syndrome.

Growth Hormone therapy will not be considered medically necessary for the following conditions and requests will be denied: Small for gestational age (SGA), unless criteria met under GH deficiency-isolated, and Idiopathic short stature (ISS).

A. Panhypopituitarism

- 1. Documented deficiencies of one or more pituitary hormones; TSH, ACTH, LH/FSH, ADH.
 - a. Deficiencies in thyroid and cortisol must be treated before performance of the GH stimulation test.
- 2. Height velocity <25th percentile for age.
 - a. Requires at least 6months of growth data
 - b. Growth curve submitted
 - c. Exception neonatal hypopituitarism/hypoglycemia
- 3. MRI documenting pituitary abnormality- recommended but not required for authorization
- 4. Low IGF1/BP3 confirmatory but not required
- 5. Degree of GH deficiency documented by response to 2 GH secretagogues
 - a. Patient must be on stable doses of other replacement hormones before performing stimulation tests. Normal thyroid levels documented before testing.
 - b. <5ng/ml = severe GH deficiency and <10 = GH deficiency
 - c. Exception neonatal hypopituitarism/hypoglycemia where either GH peak <10ng/ml during documented hypoglycemia is indication of GH deficiency or documented structural abnormalities of the pituitary/hypothalamus (ectopic neurohypophysis, septooptic dysplasia, or other midline defects). Deficiency can be documented by failure to respond to secretagogues but is not required.

B. GH deficiency-isolated

- 1. Height velocity <25th percentile for age
 - a. Requires at least 6months of growth data.
 - b. Growth curve submitted.
 - c. Exception neonatal hypopituitarism/hypoglycemia
- 2. IGF1/BP3 confirmatory but not required
- 3. Normal thyroid function tests

- 4. Failure to respond to 2 GH secretagogues with peak <10ng/ml
 - a. Documented normal thyroid function tests before stimulation test
 - b. MRI required for neonatal GH deficiency and those with peak <5ng/ml
 - c. Exception neonatal hypopituitarism/hypoglycemia where either GH peak <10ng/ml during documented hypoglycemia is indication of GH deficiency or documented structural abnormalities of the pituitary/hypothalamus (ectopic neurohypophysis, septooptic dysplasia, or other midline defects)

C. Chronic renal insufficiency

- 1. Confirmed diagnosis of CRI by Pediatric Nephrologist
- 2. HV <25th percentile for age
 - a. Requires at least 6 months of growth data.
 - b. Growth curve submitted.

D. Turner Syndrome

- 1. Confirmed diagnosis of Turner syndrome by karyotype
- 2. Normal thyroid function tests
- 3. HV <25th percentile for age or height <5th percentile
 - a. Requires at least 6 months of growth data.
 - b. Growth curve submitted.

E. Prader Willi Syndrome

- 1. Confirmed diagnosis of PWS by Geneticist
- 2. Normal thyroid function tests
- 3. DEXA scan for body composition
- 4. Absence of obstructive sleep apnea by sleep study or treated obstructive sleep apnea
- 5. HV <25th percentile for age or height <5th percentile
 - a. Requires at least 6 months of growth data.
 - b. Growth curve submitted.

All approved initial requests will be granted for 6 months.

Kansas Medicaid Prior Authorization for Renewal of Growth Hormone in Children

A. Renewal of GH in children

- 1. History and physical notes, and growth curve from pediatric endocrinologist dated within 6 months of request
- 2. Documented catch-up growth unless at target height percentile at which time growth will parallel the normal growth curve

B. Rationale for discontinuing GH therapy

- 1. Growth velocity <2cm/year while on GH therapy
- 2. Noncompliance with GH therapy plan
- 3. Recommendations of treating pediatric nephrologist or endocrinologist due to changes in underlying conditions
- 4. Failure to show change in body composition, lipid profile, or growth rate in PWS

All approved renewal requests will be granted for one year

Kansas Medicaid Prior Authorization for Growth Hormone in Adults

A. Diagnosis of pituitary insufficiency confirmed by growth hormone stimulation test (< 5ng/ml serum concentration) and below normal IGF-1/IGFBP3 except for panhypopituitarism patients including those with surgical or radiological eradication of pituitary confirmed by MRI or CT scan. It is mandatory that care must be evaluated and managed by an endocrinologist.

All approved requests will be granted open ended.

Criteria recommended by the Drug Utilization Review Committee	
Drug Utilization Review Program Manager	Pharmacy Program Manager, Division of Health Policy and Finance
Date	Date